K103455

510(k) Summary for the Lutronic Corporation SPECTRA Laser System

APR 2 8 2011

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter:

Lutronic Corporation
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Goyang-si, Gyeonggi-do, 410-72
Republic of Korea

Contact Person:

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Vice President
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Princeton Junction, NJ 08550
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Summary Preparation Date: April 2, 2011

2. Names

Device Name: SPECTRA Q-Switched Nd:YAG Laser System with Dye Handpieces

Classification Name: Laser Instrument, Surgical, Powered
Product Code: GEX
Panel: General & Plastic Surgery

3. Predicate Devices

The SPECTRA Laser System is substantially equivalent to the Lutronic Corporation Spectra VRMIII Laser System (K080248) and the Fotona QX Nd:YAG/KTP Laser System Family (K0838889).

4. Device Description

The SPECTRA Laser System produces a pulsed beam of coherent near infrared (1064 nm) and visible (532nm) light. This beam is directed to the treatment zone by means of an articulated arm coupled to a handpiece. In addition, two dye handpieces are available that convert the 532 nm wavelength to 585 nm and 650 nm.

When the beam contacts human tissue, the energy in the beam is absorbed, resulting in a very rapid, highly localized temperature increase to the target chromospheres such as melanin and tattoo particles. This increases localized temperature of the chromospheres. The instantaneous temperature increase causes fragmentation of the chromospheres to smaller particles.

By directing the beam onto specific tissue locations, using different handpieces, and controlling the treatment fluence, the intensity of the temperature of the target can be varied. The physician can optimize the effect for different applications by controlling the energy of the laser pulse and the spot size of the treatment beam.

5. Indications for Use

The SPECTRA Laser System is indicated for the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):

- -Tattoo removal: light ink (red, tan, purple, orange, sky blue, green)
- -Removal of Epidermal Pigmented Lesions
- -Removal of Minor Vascular Lesions including but not limited to telangiectasias
- -Treatment of Lentigines
- -Treatment of Café-Au-Lait
- -Treatment of Seborrheic Keratoses
- -Treatment of Post Inflammatory Hyper-Pigmentation
- -Treatment of Becker's Nevi, Freckles and Nevi Spilus

1064nm Wavelength:

- -Tattoo removal: dark ink (black, blue and brown)
- -Removal of Nevus of Ota
- -Removal or lightening of unwanted hair with or without adjuvant preparation.
- -Treatment of Common Nevi
- -Skin resurfacing procedures for the treatment of acne scars and wrinkle

6. Performance Data

None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 2 8 2011

Lutronic Corporation
% Lutronic Incorporated
Jhung Won Vojir, Ph.D.
51 Everett Drive, Unit A50
Princeton Junction, New Jersey 08550

Re: K103455
Trade/Device Name: SPECTRA Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: April 2, 2011
Received: April 5, 2011

Dear Dr. Vojir:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 103455

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Prescription Use X AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MKM Page 1 of 1
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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